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(21) International Application Number: PCT/US95/02085 (22) International Filing Date: 17 February 1995 (17.02.95) (30) Priority Data: 08/198,928 22 February 1994 (22.02.94) US (71) Applicant: KIMBERLY-CLARK CORPORATION [US/US]; 401 North Lake Street, Neenah, WI 54956 (US). (72) Inventor: COHEN, Bernard; 381 Lakeshore Drive, Berkeley Lake, GA 30136 (US). (74) Agents: ALEXANDER, David, J. et al.; Kimberly-Clark Corporation, 401 North Lake Street, Neenah, WI 54956 (US).		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: IMPROVED NONWOVEN BARRIER AND METHOD OF MAKING THE SAME (57) Abstract A steam sterilizable nonwoven material which is subjected to charging, and more particularly electrostatic charging is provided. The nonwoven materials may include laminate nonwovens wherein one or more layers are subjected to charging. The nonwoven material(s) may also be treated with an antistatic material before or after subjecting the same to charging.		

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IMPROVED NONWOVEN BARRIER
AND
METHOD OF MAKING THE SAME

5

FIELD OF THE INVENTION

The present invention is directed to bacterial barrier fabrics. More particularly, the present invention is directed to nonwoven bacterial barrier fabrics for use as sterilization wrap, surgical draping, surgical gowns, cover garments, such as over-suits, and the like.

BACKGROUND OF THE INVENTION

As is generally known, surgical gowns, surgical drapes, surgical face masks and sterile wrap (hereinafter collectively "surgical articles") have been designed to greatly reduce, if not prevent, the transmission through the surgical article of liquids and/or airborne contaminants. In surgical procedure environments, such liquids sources include the gown wearer's perspiration, patient liquids, such as blood and life support liquids such as plasma and saline. Examples of airborne contaminants include, but are not limited to, biological contaminants, such as bacteria, viruses and fungal spores. Such contaminants may also include particulate material such as, but not limited to, lint, mineral fines, dust, skin squames and respiratory droplets. A measure of a fabrics ability to prevent the passage of such airborne materials is sometimes expressed in terms of "filtration efficiency".

Many of these surgical articles were originally made of cotton or linen and were sterilized prior to their use in the operating room. Such surgical articles fashioned from these materials, however, permitted transmission or "strike-through" of various liquids encountered in surgical procedures. In these instances, a path was established for transmission of biological contaminants, either present in the liquid or subsequently contacting the liquid, through the surgical article. Additionally, in many instances

surgical articles fashioned from cotton or linen provide insufficient barrier protection from the transmission therethrough of airborne contaminants. Furthermore, these articles were costly, and of course laundering and sterilization procedures were required before reuse.

Disposable surgical articles have largely replaced linen surgical articles. Advances in such disposable surgical articles include the formation of such articles from totally liquid repellent fabrics which prevent strike-through. In this way, biological contaminants carried by liquids are prevented from passing through such fabrics. However, in some instances, surgical articles formed from nonporous films, while being liquid and airborne contaminate impervious, are, or become over a period of time, uncomfortable to wear.

In some instances, surgical articles fashioned from liquid repellent fabrics, such as fabrics formed from nonwoven polymers, sufficiently repel liquids and are more breathable and thus more comfortable to the wearer than nonporous materials. However, these improvements in comfort and breathable provide by such nonwoven fabrics have generally occurred at the expense of barrier properties or filtration efficiency.

While the focus thus far has been directed to surgical articles, there are many other garment or over-garment applications, such as personal protective equipment applications, whose designers require both fabric comfort and filtration efficiency. Other personal protective equipment applications include, but are not limited to, laboratory applications, clean room applications, such as semi-conductor manufacture, agriculture applications, mining applications, and environmental applications.

Therefore, there is a need for garment materials and methods for making the same which provide improved breathability and comfort as well as improved filtration efficiency. Such improved materials and methods are provided by the present invention and will become more

apparent upon further review of the following specification and claims.

SUMMARY OF THE INVENTION

5 In response to the above problems encountered by those of skill in the art, the present invention provides a steam sterilizable nonwoven material, such as nonwoven fabrics, formed from polymer fibers. The nonwoven materials of the present invention are formed by subjecting a portion of the
10 nonwoven material to charging, and more particularly to electrostatic charging, and then steam sterilizing the nonwoven material. The nonwoven material may be subjected to charging followed by steam sterilization or steam sterilization followed by charging. The nonwoven material
15 may also be treated with an antistatic material before or after subjecting the nonwoven material to charging.

 These methods further include positioning another nonwoven material in a juxtaposed relationship with the first nonwoven material. Portions of the other, or second,
20 nonwoven material may be subjected to charging before or after steam sterilization. The second nonwoven material may also be treated with an antistatic material before or after being subjected to charging.

 The nonwoven materials includes a steam sterilized web
25 formed from fibers of a polymer wherein a portion of these fibers have been subjected to charging, and particularly electrostatic charging. The steam sterilized nonwoven composition may also include an antistatic material present about portions thereof. The above nonwoven composition may
30 further include a second web in a juxtaposed relationship to the first web. The second web may be formed from polymer fibers wherein a portion of these fibers may be subjected to charging. An antistatic treatment may also be present about portions of the second web.

35 The composition of the present invention further includes a nonwoven material including a first web formed from fibers of a polymer, wherein a portion of these fibers

have been subject to charging and wherein an antistatic material is present about portions of the first web. This composition may further include a second web formed from fibers of a polymer, wherein the polymer is positioned in a juxtaposed relationship with the first web. The second web may also be subjected to charging.

DETAILED DESCRIPTION OF THE INVENTION

Disclosed herein are compositions, and methods of making the same, which improved both the airborne contaminate barrier and filtration efficiency of a web formed from polymer fibers. Among the applications for such compositions and methods are included, but not limited to, applications requiring sterilizable, breathable materials having high airborne contaminate barrier properties. Such materials have application in surgical articles, such as gowns, drapes, sterile wrap and face mask, as well as other non-surgical applications such as agriculture, mining, clean room and environmental.

Polymers are well suited for the formation of nonwoven materials which are useful in the practice of the present invention. Nonwoven materials can be made from a variety of processes including, but not limited to, air laying processes, wet laid processes, hydroentangling processes, spunbonding, meltblowing, staple fiber carding and bonding, and solution spinning. The fibers themselves can be made from a variety of dielectric materials including, but not limited to, polyesters, polyolefins, nylon and copolymer of these materials. The fibers may be relatively short, staple length fibers, typically less than 3 inches, or longer more continuous fibers such as are produced by a spunbonding process.

It has been found that nonwovens formed from polyolefin-based fibers are particularly well-suited for the above applications. Examples of such nonwovens are the polypropylene nonwovens produced by the Assignee of record, Kimberly-Clark Corporation. And more particularly, the

spunbond, meltblown, spunbond material produced by Kimberly-Clark Corporation.

5 This spunbond, meltblown, spunbond material may be made from three separate layers which are laminated to one another. Such a method of making this laminated material is described in commonly assigned U.S. Patent NO. 4,041,203 to Brock et al which is incorporated herein in its entirety by reference. Alternatively, the spunbond, meltblown, spunbond material may be made by first forming a spunbond, meltblown
10 laminate. The spunbond, meltblown laminate is formed by applying a layer of meltblown on to a layer of spunbond. The second layer of spunbond is then applied to the meltblown side of the previously formed spunbond, meltblown laminate. Generally, the two outer layers provide the
15 nonwoven fabric with strength while the inner layer provides barrier properties.

The nonwoven web of the present invention may be formed from a single layer or multiple layers. In the case of multiple layers, the layers are generally positioned in a
20 juxtaposed or surface-to-surface relationship and all or a portion of the layers may be bound to adjacent layers. The nonwoven web may also be formed from a plurality of separate nonwoven webs wherein the separate nonwoven webs may be formed from single or multiple layers. In those
25 instances where the nonwoven web includes multiple layers, the entire thickness of the nonwoven web may be subjected to charging or individual layers may be separately subjected to charging and then combined with other layers in a juxtaposed relationship to form the finished nonwoven
30 web.

Methods of subjecting a material to charging, and particularly electrostatic charging, are well known by those skilled in the art. These methods include, for example, thermal, liquid-contact, electron beam and corona
35 discharge methods. One particular technique of subjecting a material to electrostatic charging is the technique disclosed in U.S. Patent Application No. 07/958,958 filed

October 9, 1992 which is assigned to the University of Tennessee, and is herein incorporated in its entirety by reference. This technique involves subjecting a material to a pair of electrical fields wherein the electrical
5 fields have opposite polarities.

Sterilization of the nonwoven web may be accomplished by several techniques which include chemical and steam techniques. In those instances when the nonwoven web is used to wrap surgical instruments, steam sterilization
10 techniques are commonly used. In such instances, the unsterile instruments are first wrapped in the nonwoven web. The wrapped instruments are then steam sterilized. The instruments, still wrapped, are then removed from the steam sterilizing equipment or autoclave and are stored in
15 the wrapping material until needed. When needed, the wrapping web is removed making the instruments available for handling.

The steam sterilization cycle may vary dependent upon type of sterilizer and the size/quantity of the items being
20 sterilized. For example, the time and temperature parameters for gravity-displacement cycles may range from 10 to 15 minute exposure time at 270 °F to 275 °F to 15 to 30 minute exposure time at 250 °F to 254 °F. For pre-vacuum cycles, the time and temperature parameters may be
25 3 to 4 minutes at 270 °F to 275 °F. And for steam-flush pressure-pulse cycles, the time and temperature parameters may range from 3 to 4 minutes at 270 °F to 275 °F to 20 minutes at 250 °F to 254 °F.

In those instances where the nonwoven web is used in
30 or around flammable materials and static discharge is a concern, the nonwoven web may be treated with any number of antistatic materials. In these instances, the antistatic material may be applied to the nonwoven by any number of techniques including, but not limited to dipping the
35 nonwoven into a solution containing the antistatic material or by spraying the nonwoven with a solution containing the antistatic material. In some instances the antistatic

material may be applied to both the external surfaces of the nonwoven and the bulk of the nonwoven. In other instances, the antistatic material may be applied to portions of the nonwoven, such as a selected surface or surfaces thereof.

Of particular usefulness is the antistatic material known as ZELEC[®], an alcohol phosphate salt product of the Du Pont Corporation. The nonwoven web may be treated with the antistatic material either before or after subjecting the web to charging. Furthermore, some or all of the material layers may be treated with the antistatic material. In those instances where only some of the material layers are treated with antistatic material, the non-treated layer or layers may be subjected to charging prior to or after combining with the antistatic treated layer or layers.

To demonstrate the attributes of the present invention, the following Examples are provided.

Example 1

Kimberly-Clark manufactures a series of single sheet laminate nonwoven web materials made from spunbond-meltblown-spunbond (SMS) layers. These materials are available in a variety of basis weights. The nonwoven web materials used in Examples 1 and 2 were such single sheet laminate materials sold by Kimberly-Clark under the mark KIMGUARD[®] Heavy Duty Sterile Wrap. The basis weight of this material is 2.2 oz/sq yd. Both spunbond layers have a basis weight of 0.85 oz/sq yd and the meltblown layer has a basis weight of 0.50 oz/sq yd.

The method used to subject the samples reported in Tables 1-4 to electrostatic charging is described in the above referenced U.S. Patent Application No 07/958,958.

Referring now to Table 1, a summary of bacterial filtration efficiency (BFE) test results and standard deviation (SD) are reported for three categories

investigated for Heavy Duty KIMGUARD® Sterile Wrap. The first category, "Uncharged" reports the average BFE for eleven samples of ZELEC treated and eleven samples of non-ZELEC® treated KIMGUARD® material. These samples were not subjected to electrostatic charging or steam sterilization.

The second category, "Charged", reports the average BFE for eleven samples of ZELEC® treated and eleven samples of non-ZELEC® treated KIMGUARD® material which were subject to electrostatic charging but not steam sterilization.

The third category, "Charged/Sterilized" reports the average BFE for eleven samples of ZELEC® treated and eleven samples of non-ZELEC® treated KIMGUARD® material which were first charged then steam sterilized. Sterilization of these samples was accomplished in an Amsco 2021 Gravity Sterilizer, a product of American Sterilizer Co. of Erie, PA. Samples were sealed in a Baxter DUAL PEELTM Self Seal Pouch. The sealed pouches were exposed to 250 °F at 15 psi steam for 20 minutes with a dry time of 5 minutes. After sterilizing, the above samples were analyzed by Nelson Laboratories for Bacterial Filtration Efficiency testing.

Table 1

Bacterial Filtration Efficiency
(KIMGUARD® Heavy Duty Sterile Wrap)

<u>Description</u>	<u>Uncharged</u>	<u>Charged</u>	<u>Charged/Sterilized</u>
ZELEC®	85.55+/-2.38	93.85+/-3.67	95.87+/-0.99
Non-ZELEC®	82.18+/-1.66	96.36+/-1.72	93.64+/-2.72

As previously stated, Nelson Laboratories of Salt Lake City, UT performed the above BFE analysis. The procedure used to determine these BFEs is described in Nelson Laboratories' Protocol No. ARO/007B in accordance with MIL Spec 36954C, 4.4.1.1.1 and 4.4.1.2.

Example 2

Further analysis of the Heavy Duty KIMGUARD Sterile Wrap (2.2 oz) were conducted to determine BFE and the charge on the samples for both pre- and post- steam sterilizing. Steam sterilization of the samples reported in Example 2 was accomplished using the steam sterilization procedure reported in Example 1. The BFE results reported in Table 2 were the product of Nelson Laboratories using the protocol described in Example 1. These BFE results represent the average of eleven non-antistatic treated samples.

Table 2

Bacterial Filtration Efficiency
(KIMGUARD® Heavy Duty Sterile Wrap)

<u>Description</u>	<u>BFE</u>	<u>SD%</u>	<u>Charge Pre</u>	<u>Charge Post</u>
Uncharged	90.6	2.3	--	--
Charged	98.8	0.31	800-1000 v/cm ²	--
Charged /Sterilized	94.4	2.0	--	100-180 v/cm ²

After charging but before steam sterilizing, a voltage of between 800 to 1,000 volts/cm², positive on one side of the material and negative on the other side of the material, was recorded. After steam sterilizing, a voltage of between 100 to 180 volts/sq cm, positive on one side and negative on the other side, was recorded. In both instances, voltage was measured using an Electrostatic Voltmeter (Trek Model 344, Trek, Inc, Median, NY) by taking ten readings on each side of the samples.

Example 3

Further barrier properties for SMS fabric samples were investigated. Table 3 reports the barrier property results for KIMGUARD® Heavy-Duty Sterile Wrap (KIM) and SPUNGUARD® Regular Sterilization Wrap (SPU). SPUNGUARD® Regular Sterilization Wrap is also a spunbond, meltblown, spunbond material having a basis weight of 1.05 oz/sq yd (0.35/0.35/0.35). These categories included ZELEC® treated and non-ZELEC® treated materials, charged and non-charged, sterilized and non-sterilized material.

The charged and sterilized samples were prepared according to the charging and sterilizing procedures described in Example 1 except that all sterilized sample pouches were conditioned at laboratory ambient environment for at least 4 hours prior to testing. For samples 1 and 2, the barrier properties were measured using the Nelson procedures described in Example 1. For samples 3 - 13, the barrier properties were measured using a microbial challenge procedure described below.

In runs 3 - 13, a six port exposure chamber was used. Five of the ports accommodated five separate samples. The challenge control filter material was positioned in the sixth port. Three conditions were maintained in the microbial challenge test. These were: first, a 2.8 LPM (Liters Per Minute) flowrate through each of the ports; second, an exposure time of fifteen minutes followed by a chamber exhaust of fifteen minutes, and; third, a microbial challenge that results in 1×10^6 CFU's (Colony Forming Units) per port. *Bacillus subtilis* ss *globigii* spores, purchased from Amsco (Part No. NA-026, P-764271-022) was used to make the working spore suspension of 1×10^6 CFUS per port recovery.

Table 3

	Sample	Product	ZELEC	Charged	Sterilized	Avg%Red	SD	n
5	1	SPU	No	No	Yes	71.5	9.1	25
	2	SPU	No	Yes	Yes	87.2	3.1	25
	3	KIM	Yes	No	Yes	69.4	5.7	15
	4	KIM	Yes	Yes	Yes	80.8	9.1	15
10	5	KIM	Yes	Yes	No	97.2	1.1	15
	6	KIM	Yes	No	Yes	80.1	9.2	15
	7	KIM	Yes	Yes	Yes	88.9	5.7	15
	8	KIM	Yes	Yes	No	94.6	2.7	15
15	9	KIM	Yes	No	Yes	73.9	7.6	15
	10	KIM	Yes	Yes	Yes	86.2	4.1	15
	11	KIM	No	No	Yes	66.8	11.9	15
20	12	KIM	No	Yes	Yes	94.5	2.8	15
	13	KIM	No	Yes	No	98.2	0.7	15

n - Number of fabric samples.

25 The average percent reduction (Avg%Red) is a measurement
of filtration efficiency. The Avg%Red is an expression of
the reduction of number of colony forming units (CFUs) or
bacteria passing through a sample compared to the number
CFUs in the challenge control filter material. The Avg%Red
30 was calculated by subtracting the number of CFUs passing
through a sample from the number of CFUs passing through
the challenge control filter material and dividing this
number by the number of CFUs for the challenge filter
material. The result was then multiplied by 100 to convert
35 to percent.

Table 3 demonstrates that filtration properties of the
steam sterilized nonwoven samples are improved by of the
charging the fabric samples (Samples 2, 4, 7, 10, and 12)
as compared to samples which have not been subjected to
40 charging (Samples 1, 3, 6, 9, and 11).

Example 4

Table 4 reports charge data for the top and bottom surfaces of 2.2 oz. KIMGUARD® fabric samples subjected to various conditions. As noted in Table 4, one of the KIMGUARD® samples was treated with ZELEC® and the other was not. Except as otherwise indicated, the measurements were made on separate samples. Each sample was had a general dimension of about 10" X 10". The area of each sample measured had a general dimension of about 6" X 6". Measurements were taken each 1/2" in a 12 X 12 matrix. The charge number reported is an averaged number. The equipment used to measure charge was the same as described in Example 2.

15

TABLE 4AVERAGE SURFACE VOLTAGE OF SAMPLES OF 2.2 OZ KINGGUARD® STERILE WRAP

Sample #	1	2	3	4	5	6
	As Received	Charge	Sterilizer 20 min. in Dual Peel Pouch	Sterilizer 60 min. in Dual Peel Pouch	Sample #3 No Pouch Sterilizer 20 min.	Sample #4 No Pouch Sterilizer 60 min.
Kinguard (ZELEC)	A -2.8	-125	- 51	-100	30	- 43
	B 1.6	- 15	- 48	-169	72	66
Kinguard (Non-ZELEC)	A - 61	272	239	-353	-146	-354
	B - 87	-432	-265	-243	-232	-223

Notes: Sample #5 rerun of #3 without pouch
Sample #6 rerun of #4 without pouch

As demonstrated by the above Examples, the barrier properties of steam sterilized non-woven material are improved when these materials are subjected to charging, and particularly electrostatic charging. It will be
5 further observed that the barrier properties of an antistatic treated non-woven material are improved when these materials are subjected to charging, and particularly electrostatic charging.

While the invention has been described in detail with
10 respect to specific embodiments thereof, it will be appreciated that those skilled in the art, upon attaining an understanding of the foregoing, may readily conceive of alterations to, variations of and equivalents to these embodiments. Accordingly, the scope of the present
15 invention should be assessed as that of the appended claims and any equivalents thereto.

What is claimed is:

1. A method of manufacturing nonwoven material comprising:
charging a nonwoven web; and
steam sterilizing the nonwoven web.
2. The method of claim 1 wherein the nonwoven web is steam sterilized prior to being charged.
3. The method of claim 1 wherein the nonwoven web is charged prior to being steam sterilized.
4. The method of claim 1 wherein the charging is electrostatic charging.
5. The method of claim 1 further including the step of treating the web with an antistatic material.
6. The method of claim 1 wherein the nonwoven material comprises first and second nonwoven webs joined together in juxtaposed relationship.
7. The method of claim 6 wherein the webs are joined after the charging step.
8. The method of claim 7 wherein the first web is charged and the second web is not charged.
9. The method of claim 6 wherein the first web is treated with an antistatic material.
10. The method of claim 9 wherein the second web is treated with an antistatic material.
11. A method of manufacturing nonwoven material comprising:
charging a nonwoven web; and
treating th nonwoven web with an antistatic material.

12. The method of claim 11 wherein the nonwoven web is treated with the antistatic material prior to being charged.

13. The method of claim 11 wherein the nonwoven web is charged prior to being treated with the antistatic material.

14. The method of claim 11 wherein the charging is electrostatic charging.

15. The method of claim 11 wherein the nonwoven material comprises first and second nonwoven webs joined together in juxtaposed relationship.

16. The method of claim 15 wherein the webs are joined after the charging step.

17. The method of claim 16 wherein the first web is charged and the second web is not charged.

18. A steam sterilized, nonwoven material, wherein portions thereof have been subjected to charging.

19. The nonwoven material of claim 18 wherein the nonwoven material comprises first and second nonwoven webs joined together in juxtaposed relationship.

20. A nonwoven material treated with an antistatic material wherein portions of the nonwoven material have been subjected to charging.

21. The nonwoven material of claim 20 wherein the nonwoven material comprises first and second nonwoven webs joined together in juxtaposed relationship.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 95/02085

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 004H13/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 004H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US-A-4 863 785 (BERMAN MARK H S ET AL) 5 September 1989 see column 2, line 16 - column 5, line 21 ---	1,5-7, 9-11,15
Y	PATENT ABSTRACTS OF JAPAN vol. 007 no. 167 (C-177) ,22 July 1958 & JP,A,58 076118 (KOUKEN KK) 9 May 1983, see abstract ---	1,5-7, 9-11,15
A	PATENT ABSTRACTS OF JAPAN vol. 011 no. 246 (C-439) ,11 August 1987 & JP,A,62 053719 (JAPAN VILENE CO LTD) 9 March 1987, see abstract --- -/--	1,4

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 95/02085

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>PATENT ABSTRACTS OF JAPAN vol. 011 no. 273 (C-445) ,4 September 1987 & JP,A,62 074423 (JAPAN VILENE CO LTD) 6 April 1987, see abstract</p> <p>-----</p>	1,4

Information on patent family members

International Application No

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Form PCT/ISA/210 (patent family annex) (July 1992)

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